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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/981,440 | 10/16/2001 | Michael Greenstein | 10004416 | 5699 |

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| EXAMINER | |
|---|---|
| LAM, ANN Y | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1641 | |

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/981,440 | GREENSTEIN ET AL. | |
| | Examiner | Art Unit | |
| | Ann Y. Lam | 1641 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *20 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-18,23 and 24* is/are pending in the application.

4a) Of the above claim(s) *21 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18,23 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 6-18, 23 and 24, are rejected under 35 U.S.C. 103(a) as being unpatentable over Zou et al., 6,762,049, in view of Austin et al., 6,203,683, and further in view of Laugharn et al., 6,719,449.

Zou et al. disclose the invention substantially as claimed. More specifically, as to claim 1, Zou et al. disclose a cartridge (5, see figure 4) comprising one or more portions constructed of a material, wherein the one or more portions define an array of temperature-controlled zones ((chambers 6), see col. 2, line 67) including reactants (col. 4, line 13), and wherein each said temperature-controlled zone is constrained by cartridge portions that surround an area of space in which a reactant is contained and confine the reactant from flowing into other of said temperature-controlled zones (fig. 4, disclosing each chamber 6 to be isolated from other chambers);

an array of heat source ((13), see fig. 4) wherein the array of heat sources is positioned to correspond to the array of temperature-controlled zones so that each heat source is arranged to provide temperature regulation to a corresponding temperature-

controlled zone, and wherein one or more of the heat sources emit localized radiation to provide heating in the corresponding temperature-controlled zones (col. 2, lines 63-67, disclosing an array of blocks for each chamber (6), and col. 3, lines 63-66, disclosing heater and sensor (13) on the top of each block (1));

a temperature monitor that monitors reactant temperature (sensor 13, col. 3, lines 54-64—the Office notes that sensor 13 is disclosed as heater and sensor); and

a modulator that modulates the array of heat sources to regulate temperature in one or more of the corresponding temperature-controlled zones (col. 2, lines 42-43, disclosing individually controlled heaters and sensors);

whereby each temperature-controlled zone is controllable to a designated temperature (col. 1, lines 53-54, and col. 2, lines 42-43, disclosing independently and individually controlled heaters and sensors),

and wherein the temperature monitor (13) is not in contact with the cartridge (5) and is disposed adjacent to a portion of the cartridge surrounding the temperature controlled zones (see figure 4). (The Office notes that the heaters (13) are not in contact with the substrate (5) because of element (15), see figure 4 and col. 3, lines 63-65)

However, Zou et al. do not teach that the temperature monitor is an optical temperature monitor that measures electromagnetic radiation. (Rather, Zou et al. teach that the temperature monitor is a resistive material (col. 3, line 54-56).

However, Austin et al. teach that a wire (i.e., resistive heater) can be used to heat an array of chambers for holding reactants and that heating could also be achieved

by infrared light sources shining on the chip (col. 8, lines 10-15). Thus, Austin et al. teach that resistive heaters and infrared light sources are functional equivalents in heating an array of chambers for holding reactants. Moreover, both Zou et al. and Austin et al. teach that the chambers are for DNA analysis (see Zou et al., col. 5, lines 46-48, and Austin et al., col. 2, lines 45-46). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide infrared light sources to heat the chambers in the Zou et al. invention because Austin et al. teach that infrared light sources is a functional equivalent to resistive heaters, such as the heaters in the Zou et al. invention, for heating reaction chambers for analyses such as DNA analyses.

Moreover, Laugharn et al. teach that heating of individual wells can be determined by an infrared temperature-sensing probe. Laugharn et al. teach that for example, an infrared thermal measuring device can be directed at the top of a vessel and that this provides non-contact means of analysis. Laugharn et al. also teach that temperature monitoring may be used as a feedback mechanism to modify the temperature (col. 18, line 64 – col.19, line 16.) Thus, Laugharn et al. teach that an infrared temperature-sensing probe may be provided as a non-contact means of analysis. Thus, one of ordinary skill in the art would have a reasonable expectation of success in modifying the Zou et al. reference to provide an infrared heater and sensor, given the teachings of Laugharn that an infrared thermal measuring device provides a non-contact means of analysis.

As to claims 10-12, 14-18 and 24, Zou et al. teach the limitations as follows.

As to claim 10, the array of heat sources comprises internal heat generators (13).

As to claim 11, the internal heat generators comprise resistive heaters (col. 5, lines 14-15), inductive heaters or Peltier heaters.

As to claim 12, an array of electrical leads (16, col. 3 line 66 – col. 4, line 1) correspond with the internal heat generators.

As to claim 14, a power supply drives current to increase the temperature of the zones (col. 2, lines 42-43, and col. 5, lines 14-15).

As to claim 15, a controller coupled to said power supply controls the drive current (col. 2, lines 42-43, and col. 5, lines 14-15).

As to claim 16, the controller modulates the power supply based on a temperature measured from the temperature-controlled zones (col. 2, lines 42-46.)

As to claim 17, an array of temperature monitors is positioned to correspond to the array of temperature controlled zones (col. 3, line 64.)

As to claim 18, said reactants comprise assay elements for body fluid analysis (see Zou et al., col. 1, lines 12-13, and lines 52-59.)

As to claim 24, the heat source is capable of providing a temperature that maintained at a desired temperature.

As to claims 2, 6, 7, and 13, Austin et al. teach the limitations as follows.

As to claims 2 and 6, the infrared light sources (infrared lamp) shining directly on the chip disclosed by Austin et al., (see col. 8, line 10-15) are electromagnetic radiation emitters.

As to claim 7, the infrared light source is capable of generating infrared light of a different wavelength. (The Office notes that the claim does not recited from what it is different.)

As to claim 13, the infrared light source taught by Austin et al. is considered an external heater because it is external to the chamber.

Also, as to claims 8 and 9, neither Zou et al. nor Austin et al. disclose that the light sources generate infrared light with a wavelength of at least .775 micrometers, or at most 7000 micrometers.

Austin et al. teach that the heaters are intended for controlling the temperature for polymerase chain reaction for nucleic acid amplification (see column 1, lines 55-59.) It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 1-5 USPQ 233. In this case, Zou et al. in view of Austin et al. disclose the general conditions of the claims, and infrared light with a wavelength as claimed is a workable range and thus its discovery only involves routine skill in the art.

As to claim 23, while Zou et al. teach heating and sensing temperature of a reaction chamber, Zou et al. do not specifically disclose a feedback loop including use of the reactant temperature to modulate a power supply that drives the array of heat sources. This feedback loop however is disclosed by both Austin et al. (col. 11, lines 7-19) and Laugharn et al. (col. 19, lines 6-16). It would have been obvious to one of ordinary skill in the art to provide a feedback loop as taught by Austin et al. and/or

Laugharn et al. as a means to regulate the heater as would be desirable for maintaining controlled temperature in analyses such as DNA analyses.

**IV.** Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zou et al., 6,762,049, in view of Austin et al., 6,203,683, and Laugharn et al., 6,719,449, as applied to claim 2, and further in view of Miyazaki et al., 5,599,502.

Zou et al. in view of Austin et al. and Laugharn et al. disclose the invention substantially as claimed (see above), except for the infrared light source being a laser. (Austin et al. teaches an infrared light source but does not specifically disclose that the light source is a laser.)

Miyazaki et al. discloses a heat source producing infrared light for heating liquid during a reaction can be an infrared laser (col. 6, lines 23-28, and col. 9, lines 4-34.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an infrared laser as taught by Miyazaki et al. as the infrared light source in the invention taught by Zou et al. in view of Austin et al. and Laugharn et al. because Miyazaki et al. teach that a laser producing infrared light provides the advantage of heating liquid during a reaction, such as the reaction in the Zou et al. invention, and an infrared laser is a type of infrared light source that is generally disclosed by Austin et al. and Laugharn et al.

***Response to Arguments***

Applicant's argument with respect to the rejections of the above claims are moot in view of the new grounds of rejection.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.

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03/20/06